NIPRO MEDICAL CORPORATION
3150 N.W. 107 Avenue
Miami, Florida 33172
Tel.: (305) 599-7174
Fax: (305) 599-8454

FEB 21

510(k) Summary
NIPRO Transducer Protector TP-SURE

807.92(a) (1)

Applicant: Nipro Medical Corporation
Establishment Reg.: 1056186

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: February 21, 2008

807.92(a) (2)

Trade Name: NIPRO Transducer Protector TP-SURE
Common Name: Transducer Protector
Classification Name: protector, transducer, dialysis
Regulation Number: 21 CFR 876.5820
Panel: 78
Product Code: FIB

807.92(a) (3)

Legally marketed substantial equivalent device:
K983076 – Medisystems Transducer Protectors
K072024 - NIPRO Set - Blood Tubing Set with transducer protectors and priming set.

807.92(a) (4)

Description of device:
The Nipro Transducer Protector TP-SURE consists of a plastic housing that contains a hydrophobic filter with a reference pore size of 0.1 μm. The housing has male and female luer lock connectors that allow its attachment between a blood tubing set and the pressure monitor on a hemodialysis machine.

The TP-SURE is to be used as protective device for pressure monitors as well as to help maintain the sterility of the blood tubing fluid pathway. The 0.1 μm hydrophobic filter helps prevent cross-contamination by viruses, bacterial and particulate matter while preventing the flow of fluids to the hemodialysis machine pressure monitor.

The devices are packaged sterile and labeled for single use only. There is no ability to clean and reuse these devices. They are restricted for sale by or on the order of a physician.

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807.92(a) (5)

Indications for Use:

The Nipro Transducer Protector TP-SURE is a single-use, disposable, prescription device intended for use as a protective device for pressure monitors and to help prevent contamination of the fluid pathway in hemodialysis delivery systems.

807.92(a) (6)

Comparison of technological characteristics:

The NIPRO Transducer Protector TP-SURE is substantially equivalent to the predicate device in the following technological characteristics –

- Design
- Physical characteristics
- Basic Scientific Technology
- Intended Use

807.92(b) (1)

Non-clinical tests submitted:

Performance testing was conducted to verify that the device is safe and effective for its intended use. Those tests along with their associated results and conclusions are included in this submission. Biocompatibility testing was also conducted. Those tests include cytotoxicity, pyrogenicity, acute toxicity, intracutaneous reactivity, hemolysis testing, implantation testing and bacterial endotoxin testing.

807.92(b) (3)

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the NIPRO Transducer Protector TP-SURE performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Ms. Jessica Oswald
Regulatory Affairs Specialist
NIPRO Medical Corporation
3150 N.W. 107 Avenue
MIAMI FL 33172

Re: K072988
Trade/Device Name: NIPRO Transducer Protector TP-SURE
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIB
Dated: February 14, 2008
Received: February 15, 2008

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K072988

Device Name: NIPRO Transducer Protector TP-SURE

Indications for Use:

The Nipro Transducer Protector TP-SURE is a single-use, disposable, prescription device intended for use as a protective device for pressure monitors and to help prevent contamination of the fluid pathway in hemodialysis delivery systems.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072988